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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,642	09/18/2003	Cai-Zhong Jiang	MBI-0054	9792
47334	7590	05/18/2006	EXAMINER	
MENDEL 2 C/O MOFO SF 425 MARKET STREET SAN FRANCISCO, CA 94066			BAUM, STUART F	
			ART UNIT	PAPER NUMBER
			1638	
DATE MAILED: 05/18/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/666,642

Applicant(s)

JIANG ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-29 and 31-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-29 and 31-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The amendment and 1.132 Declaration of Peter Repetti filed 2/16/2006 have been entered.
2. Claims 21-29, and 31-40 are pending.  
Claims 1-20 and 30 have been canceled.
3. Claims 21-29 and 31-40 including amino acid coordinates 111-164 of SEQ ID NO:194 are examined in the present office action.
4. Rejections and objections not set forth below are withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

### ***Written Description***

6. Claims 21-29 and 31-40 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 10/11/2005. Applicant's arguments filed 2/16/2006 have been fully considered but they are not persuasive.

Applicants contend "it is a well-known principle that regulatory (and other) sequences that are closely related, having descended from a common ancestral sequence, often share similar functions" (page 13 of Remarks, 7<sup>th</sup> paragraph). Applicants contend plants overexpressing G1274-like sequences produced similar morphological and physiological characteristics, i.e., flat leaves for 13 of 20 sequences tested; short stature, 18 of 20 sequences tested; bushy appearance,

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17 of 20 sequences tested; increased biomass, 16 of 20 sequences tested; increased water deprivation tolerance 14 of 20 sequences tested; low nitrogen tolerance, 13 of 20 sequences tested; cold tolerance, 11 of 20 sequences tested (page 14, top paragraph). Applicants contend that all 20 sequences conferred the characteristic G1274-like morphological and physiological phenotypes and Applicants further stated “thus confirming the related, conserved functions of these sequences and their ability to affect common regulatory pathways” (page 14 of Remarks, 1<sup>st</sup> full paragraph). Applicants contend that conserved domains can be identified and that conserved domains may be used as predictors of evolutionary relationship and function (page 14 of Remarks, 3<sup>rd</sup> full paragraph). Applicants contend “The linkage between conserved domains and function is underscored by that fact that gene sequences and encoded polypeptides need not be full length, so long as the desired functional domain of the protein is expressed” (page 15 of Remarks, top paragraph). Applicants contend the specification is replete with descriptions and definitions of conserved domains (*Ibid*). Applicants contend “Conserved domains such as conserved DNA binding domains may be used to identify phylogenetically-related sequences that have a minimum (e.g., 70% or more) sequence identity with the similar domain in G1274...” (page 15 of Remarks, bottom paragraph). Applicants contend that this approach was taken to identify G1274 as a member of the WRKY family of transcription factors (*Ibid*). Applicants contend, “[t]he first step in making functional predictions is the generation of a phylogenetic tree representing the evolutionary history of the gene of interest and its homologs. After the tree is inferred, biologically determined functions of the various homologs are overlaid onto the tree” (page 16 of Remarks, 1<sup>st</sup> full paragraph). Applicants contend that the specification discloses how to identify homologous, paralogous or orthologous sequences in another plant (page 16 of

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Remarks, bottom paragraph). Applicants contend when using a phylogenetic approach, the threshold of sequence similarity that distinguishes between homologs with divergent or similar functions can be ascertained (*Ibid*). Applicants contend that the declaration by Dr. Peter Repetti supports Applicants' identification of phylogenetically-related sequences from diverse species that function in a manner similar to G1274 (SEQ ID NO:194) (page 17 of Remarks, 1<sup>st</sup> full paragraph). Applicants contend the Repetti declaration discloses phylogenetically-related sequences having conserved domains that are at least 55% identical to the conserved domain of the G1274 polypeptide (*Ibid*). Applicants contend Table 7, page 185, rows 3-12, list examples of closely-related sequences possessing conserved domains similar to that of G1274 and of these, four of them have been shown to confer some of the disclosed phenotypes when overexpressed in a plant (page 17 of Remarks, 2<sup>nd</sup> full paragraph).

Peter Repetti states "Based on the limited tests performed thus far, a minority of the sequences within the G1274 clade, which have conserved domains at least 74% identical to the conserved domain of G1274, including G3728, G3719, G3730, and G3723, has not yet conferred traits similar to those conferred by G1274 in morphological or physiological assays in a significant number of plants. However, as noted below, a small number of lines of plants overexpressing each of these sequences have thus far tested positive for improved traits similar to those conferred by G1274. For example:

some 35S::G3728 seedlings of one line were slightly more tolerant to desiccation than controls in a plate-based assay, and 4 of 60 lines tested produced larger seedlings than controls;

seedlings of one of four 35S::G3719 lines were larger and produced less anthocyanin than controls on low nitrogen media;

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in a cold germination assay, one of four lines of G3730 overexpressors produced larger seedlings with less anthocyanin accumulation than controls. Seedlings of this line also accumulated less anthocyanin on low nitrogen media, indicating a low nitrogen tolerant phenotype; and

seedlings of one of ten G3723 overexpressing lines were more tolerant to desiccation and mannitol (an assay then used to indicate drought tolerance). Two other lines produced larger seedlings than controls on control growth media” (page 3 of Repetti 1.132 Declaration, 1<sup>st</sup> five paragraphs).

The Office contends Applicants’ claims are drawn to plants and methods comprising a polynucleotide sequence that encodes a polypeptide having a conserved domain that has at least 70% sequence identity to the conserved domain of amino acid coordinates 111-164 of SEQ ID NO:194. To fulfill the written description requirement for Applicants’ broad claims, Applicant is required to disclose other polynucleotide sequences encoding proteins comprising the specified conserved domain, wherein the conserved domain has at least 70% amino acid identity to amino acid coordinates 111-164 of SEQ ID NO:194 at the time of filing. Or Applicants can disclose conserved domains that are sufficient and essential for the proper activity of the polypeptide.

In the instant application, Applicants have disclosed one sequence that comprises the claimed domain and has the claimed function at the time of filing. Applicants have elaborated at length the method of isolating additional sequences using a phylogentic approach. The Office appreciates Applicants’ method of identifying other sequences that are encompassed by the claims. But Applicants are not claiming a method of identifying sequences, but rather,

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Applicants are claiming plants and methods comprising the claimed sequences. Applicants are still required to disclose the above recited information.

The Office contends that Applicants have only disclosed one domain that is characteristic to the claimed genus, i.e., amino acids 111-164 of SEQ ID NO:194. The Office contends that polypeptides which have the desired function of creating plants with altered traits, as specified in claim 24, comprise other domains that are necessary for producing the claimed phenotypes. The Office contends that Applicants were not in possession of the claimed genus at the time of filing because, in part, of the disclosure of Repetti. Repetti states that four additional sequences were isolated that fall within the scope of the claimed genus, i.e., G3728, G3719, G3730, and G3723 and these sequences have not conferred all of the claimed traits when transformed into a plant (see above). Therefore, the Office contends Applicants were not in possession of the claimed genus and even using Applicants own methods, Applicants have not disclosed other sequences that fall within the scope of the claimed genus that encode a protein with the same activity/function as the protein of SEQ ID NO:194.

#### *Enablement*

7. Claims 21-29 and 31-40 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 10/11/2005. Applicant's arguments filed 2/16/2006 have been fully considered but they are not persuasive.

Applicants contend that conserved domains and functions conserved between phylogenetically-related sequences are well known in the art, as discussed above (page 18 of Remarks, 5<sup>th</sup> full paragraph). Applicants contend that the scope is supported by the specification as filed and properly dictated by the phylogenetic relatedness of the claimed sequences (page 18 of Remarks, 6<sup>th</sup> full paragraph). Applicants contend that regarding predictability of the art and the presence or absence of working examples, sequences that fall within the scope of the claims have been used to make overexpressing lines that have greater tolerance to cold during germination, greater tolerance to cold during growth, greater tolerance to water deprivation, greater tolerance to nitrogen limitation, larger leaves, and greater biomass than wild-type plants (page 18 of Remarks, 7<sup>th</sup> full paragraph). Applicants contend SEQ ID NO:969, 971, 974, and 975 have been shown to confer large size, water deprivation tolerance, cold tolerance and/or low nitrogen tolerance, as does G1274, when overexpressed in a plant (page 19 of Remarks, top paragraph). Applicants contend that one of skill in the art can predict which nucleic acids that are 70% sequence identical to amino acid coordinates 111-164 of SEQ ID NO:194 using a phylogenetic-based approach provided by Applicants. This approach identifies sequences that are derived from a common ancestor and lie within a closely-related clade (page 19 of Remarks, 1<sup>st</sup> full paragraph). Applicants contend that “orthology or phylogenetic-relatedness infers strong selection to retain a particular function” and that “Bowie et al do not address the likelihood that residues will be conserved in phylogenetically-related proteins falling within a closely-related clade” (page 19 of Remarks, 2<sup>nd</sup> full paragraph). Applicants state “proteins closely-related to G1274 should retain similar function and would be provide a plethora of functional sequences that are routine to discover” (page 20 of Remarks, top paragraph). Applicants contend that based



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on the declaration of Repetti in which the tested sequences conferred at least some, if not all of the traits conferred by G1274, the present claims would be more likely to represent operable rather than inoperable species (page 20 of Remarks, top paragraph). Applicants contend that a single mutation in a protein can result in an inoperable protein, but, functional predictions can be improved by focusing on how the genes became similar in sequence, i.e., by evolutionary process (page 20 of Remarks, 1<sup>st</sup> full paragraph). Applicants contend that organisms will retain proteins with desired functions that have evolved from ancestral organisms (*Ibid*). Applicants contend that the Miao reference which teaches the WRKY53 protein and its overexpression in plants does not seem to be relevant to the present rejection (page 20 of Remarks, bottom paragraph). Applicants contend that the specification discloses how to isolate the claimed sequences as evidenced by the disclosure of SEQ ID NO:969, 971, 974 and 975, which function as claimed (page 21 of Remarks, 1<sup>st</sup> full paragraph). Applicants continue by contending the required techniques are taught in high schools. Lastly, Applicants contend that all of the sequences closely-related to SEQ ID NO:194 that fall within the scope of the present claims, that are derived from evolutionarily diverse species, and that have been transformed into plants can confer similar functions when overexpressed (page 21 of Remarks, bottom paragraph).

The Office contends that Applicants' claims are broadly drawn to transgenic plants or methods comprising any nucleic acid encoding a polypeptide, wherein the polypeptide comprises a conserved domain that has at least 70% sequence identity to amino acid coordinates 111-164 of SEQ ID NO:194. Applicants have disclosed one nucleic acid sequence encoding SEQ ID NO:194 that when overexpressed in plants alters the traits listed in claim 24. Applicants have not disclosed other sequences that encode proteins comprising a conserved domain that has at

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least 70% sequence identity to amino acid coordinates 111-164 of SEQ ID NO:194 and produces a plant with all the traits listed in claim 24. Applicants have not disclosed other conserved domains that are required for the proper activity of the protein. Applicants have not disclosed how one skilled in the art distinguishes between those sequences that produce the desired traits versus those sequences that don't, even though they both encode proteins comprising a conserved domain that has at least 70% sequence identity to amino acid coordinates 111-164 of SEQ ID NO:194. For example, the protein G3729 listed in Exhibit B, exhibits 74% sequence identity in the claimed conserved domain, but plants overexpressing G3729 are not reported as having a greater tolerance to water deprivation, or greater tolerance to cold during growth, or greater biomass. The Office acknowledges Applicants' phylogenetic approach for identifying sequences that can be used in the claimed invention, but, the claims are not limited to identifying sequences according to a specific method. Therefore, isolating sequences using any method or manufacturing sequences according to any method, will produce a multitude of sequences falling within the claimed scope that have to be tested. Given the unpredictability and the state-of-the-art as stated previously, and given the lack of guidance for identifying those sequences that encode a polypeptide comprising a conserved domain that has at least 70% sequence identity to amino acid coordinates 111-164 of SEQ ID NO:194 and whose activity is such that when the nucleic acid is transformed into a plant, produces the traits that are set forth in claim 24, undue trial and error experimentation would be required by one of skill in the art to practice the claimed invention.

8. No claims are allowed.

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9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Stuart F. Baum Ph.D.

Patent Examiner

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May 12, 2006

STUART F. BAUM, PH.D.  
PATENT EXAMINER